

33700WC005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s) :
WILBUR, et al.

U.S. Serial No.: 09/750,280

Examiner:

Filed: December 29, 2000

Group Art Unit: 1625

For: TRIFUNCTIONAL REAGENT FOR
CONJUGATION TO A BIOMOLECULE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, Applicants are enclosing an Information Disclosure Citation Form (PTO-1449) that is supplemental to the Information Disclosure Statement filed in the above-identified patent application on October 11, 2001.

Also enclosed are the references that were previously cited in the Form 1449. Please note that the cited PCT patent (WO 91/01749) and the Australian patent (AU-B-64268/90) are corresponding cases.

Consideration of the foregoing and enclosures plus the return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited along with an early action on the merits.

It is respectfully requested that the cited document be considered by the Examiner in the above-identified patent application and that the cited documents be made officially of record therein. It is further requested that a listing of the same appear on the face of any patent which may issue from this application.

Respectfully submitted,

SMITH, GAMBRELL & RUSSELL, LLP

By: 

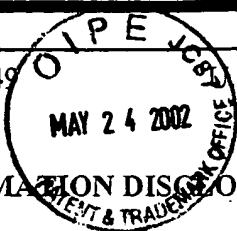
Robert G. Weilacher, Reg. No. 20,531
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Patent Trademark Office

Dated: May 24, 2002



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(Use several sheets if necessary)

APPLICANT

Wilbur, et al

FILING DATE

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GROUP

1625

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE APPROPRIAT
	A	5,474,772	12/1995	Maddock			
	B	5,541,287	7/30/96	Yau et al.			
	C	5,578,287	11/26/96	Theodore, et al.			
	D	5,482,698	1/9/96	Griffiths			
	E	5,273,743	12/28/93	Ahlem et al.			
	F	5,739,287	4/14/98	Wilbur, et al.			
	G	6,083,926	7/4/00	Morgan, Jr., et al.			
	H	5,840,880	11/24/98	Morgan, Jr., et al.			
	I	4,877,868	10/31/89	Reno, et al.			

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATIO YES NO
	J	EP 0 567 514 B1 ✓	11/1993	Europe			
	K	WO91/01749 -	02/1991	PCT			
*	L	AU-B-64268/90	03/1991	Australia			

OTHER INFORMATION (including author, title, date, pertinent pages, etc.)

	M	"Radioimmunoscinigraphy with technetium-99m-labelled monoclonal antibody, SM3, in gynaecological cancer," authored by M. Granowska, et al., featured in <i>European Journal of Nuclear Medicine</i> , Vol. 20, No. 6, June 1993, 483-489
	N	"Radioimaging of Melanoma Using ^{99m} Tc-labeled Fab Fragment Reactive with a High Molecular Weight Melanom Antigen," authored by Lamk M. Lamki, et al., featured in <i>Cancer Research (Suppl.)</i> , 50, February 1, 1990, pp. 904-908s
	O	"Clinical Studies of Cancer Radioimmunodetection with Carcinoembryonic Antigen Monoclonal Antibody Fragments Labeled with ¹²³ I or ^{99m} TC," authored by David M. Goldenberg, et al., featured in <i>Cancer Research (Suppl.)</i> , 50, February 1, 1990, pp. 909s-921s
	P	"Clinical Experience with Iodine-123-Iodophenylpentadecanoic Acid," authored by James Corbett, featured in <i>The Journal of Nuclear Medicine</i> , Vol. 35, No. 4 (Suppl), April, 1994, pp. 32S-37S
	Q	"Preliminary Report of an Ongoing Phase I/II Dose Range, Safety and Efficacy Study of Iodine-123-Phenylpentadecanoic Acid for the Identification of Viable Myocardium," authored by C. Hansen, featured in <i>The Journal of Nuclear Medicine</i> , Vol. 35, No. 4 (Suppl), April, 1994, pp. 38S-42S
	R	"Localization of Cognitive Operations in the Human Brain," authored by Michael I. Posner, et al., featured in <i>Science</i> , Vol. 240, June 17, 1988, pp.1627-1631
	S	"Cardiac SPECT with Iodine-123-Labeled Fatty Acids: Evaluation of Myocardial Viability with BMIPP," authored by F.F. (Russ) Knapp, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 36, No. 6, June, 1995, pp. 1022-10

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DATE CONSIDERED

* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

* References to be provided at a later date

PAGE 2 OF 6						
Form PTO-14 (Rev. 7-80)	U.S. Department of Commerce Patent and Trademark Office					
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)						
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FOREIGN PATENT DOCUMENTS						
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER INFORMATION (including author, title, date, pertinent pages, etc.)						
T	"Phase I/II Clinical Radioimmunotherapy with an Iodine-131-Labeled Anti-Carcinoembryonic Antigen Murine Monoclonal Antibody IgG," authored by Thomas M. Behr, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 38, No. 6 June, 1997, pp. 858-870					
U	"Phase I Radioimmunotherapy Trial with Iodine-131-CC49 in Metastatic Colon Carcinoma," authored by C.R. Divgi, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 36, No. 4 April, 1995, pp. 586-592					
V	"Yttrium-90/Indium-111-DOTA-Peptide-Chimeric L6: Pharmacokinetics, Dosimetry and Initial Results in Patient with Incurable Breast Cancer," authored by Sally J. Denardo, et al., featured in <i>Anticancer Research</i> , Vol. 17, 1997 pp. 1735-1744					
W	"Experimental Radiotherapy of Receptor-Positive Human Prostate Adenocarcinoma With ¹⁸⁸ Re-RC-160, A Direct Radiolabeled Somatostatin Analogue," authored by Paul O. Zamora, et al., featured in <i>Int. J. Cancer</i> , Vol. 65, 1999 pp. 214-220					
X	"Regulation of Tumor Cell Growth: Experimental Approaches and Clinical Oncology -- Somatostatin Analogues Somatostatin-Receptor-Mediated Radiotherapy of Cancer," authored by B. Stolz, et al., featured in <i>Digestion</i> , Vol. 57 (suppl 1), 1996, pp. 17-21					
Y	"ZD2767, an Improved System for Antibody-directed Enzyme Prodrug Therapy That Results in Tumor Regression in Colorectal Tumor Xenografts," authored by David C. Blakey, et al., featured in <i>Cancer Research</i> , Vol. 56, July 15, 1996, pp. 3287-3292					
Z	"Clearance of circulating radio-antibodies using streptavidin or second antibodies in a xenograft model," authored by Marshall, et al., featured in <i>Br. J. Cancer</i> , Vol. 69, 1994, pp. 502-507					
AA	"Immunotargeting of antioxidant enzymes to the pulmonary endothelium," authored by Vladimir R. Muzykantov, et al., featured in <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 93, May 1996, pp. 5213-5218					
AB	"Development of a Streptavidin - Anti-Carcinoembryonic antigen, Antibody, Radiolabeled Biotin Pretargeting Method for Radioimmunotherapy of Colorectal Cancer. Studies in a Human Colon Cancer Xenograft Model," authored by Robert M. Sharkey, et al., featured in <i>Bioconjugate Chem.</i> , Vol. 8, No. 4, 1997, pp. 595-604					
AC	"Rapid Blood Clearance of Biotinylated IgG after Infusion of Avidin," authored by Vladimir V. Sinityn, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 30, No. 1, January, 1989, pp. 66-69					
AD	"Galactosylated streptavidin for improved clearance of biotinylated intact and F(ab) ₂ fragments of an anti-tumour antibody," authored by D. Marshall, et al., featured in <i>British Journal of Cancer</i> , Vol. 71, 1995, pp. 18-24					
AE	"The Role of Surface Carbohydrates in the Hepatic Recognition and Transport of Circulating Glycoproteins," authored by Gilbert Ashwell, et al., featured in <i>Adv. Enzymol.</i> , Vol. 41, 1974, pp. 99-128 (Ref Missing)					
AF	"Strategies to Enhance the Localization of Anticancer Immunoconjugates," authored by George J. Schreiber, et al., featured in <i>Current Medicinal Chemistry</i> , Vol. 2, 1995, pp. 616-629					
AG	"Improved Monoclonal Antibody Tumor/Background Ratios with Exchange Transfusions," authored by Christine Henry, et al., featured in <i>Nucl. Med. Biol.</i> , Vol. 18, No. 5, 1991, pp. 565-567					
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Form PTO-1449 (Rev. 7-80) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">ATTY. DOCKET NO. 033700.005</td> <td style="width: 50%;">SERIAL NO. 09/750,280</td> </tr> <tr> <td colspan="2">APPLICANT Wilbur, et al</td> </tr> <tr> <td>FILING DATE December 29, 2000</td> <td>GROUP 1625</td> </tr> </table>	ATTY. DOCKET NO. 033700.005	SERIAL NO. 09/750,280	APPLICANT Wilbur, et al		FILING DATE December 29, 2000	GROUP 1625
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OTHER INFORMATION (including author, title, date, pertinent pages, etc.)							
	AH	"Clinical Aspects of Local and Regional Tumor Therapy with ¹⁸⁸ Re-RC-160," authored by H. Bender, et al., featur in <i>Anticancer Research</i> , Vol.17, 1997, pp. 1705-1712					
	AI	"Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin Anti-Mouse IgG Antibodies," authored by Alexander L. Klivanov, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 29, No. 12, December, 1998, pp. 1951-1956					
	AJ	"Improved Characteristics of a Human β -Glucuronidase-Antibody Conjugate after Deglycosylation for Use in Antibody-Directed Enzyme Prodrug Therapy," authored by Pieter H. J. Houba, et al., featured in <i>Bioconjugate Chem.</i> , Vol. 7, No. 5, 1996, pp. 606-611					
	AK	"Site-Specific Prodrug Activation by Antibody- β -Lactamase Conjugates: Preclinical Investigation of the Efficacy and Toxicity of Doxorubicin Delivered by Antibody Directed Catalysis," authored by Damon L. Meyer, et al., featured in <i>Bioconjugate Chem.</i> , Vol. 6, No. 4, 1995, pp. 440-446					
	AL	"Avidin and Streptavidin," authored by N. Michael Green, featured in <i>Methods in Enzymology</i> , Vol. 184, 1990, pp 51-67					
	AM	"Avidin," authored by N. Michael Green, featured in <i>Adv. Prot. Chem.</i> , Vol. 29, 1975, pp. 85-132.					
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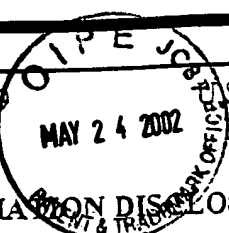
* References to be provided at a later date

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					YES	NO

OTHER INFORMATION (including author, title, date, pertinent pages, etc.)

BA	"Plasma Stability and Pharmacokinetics of Radiolabeled Deferoxamine-Biotin Derivatives," authored by Scott F. Rosebrough, featured in <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 265, No. 1, 1993, pp. 408-415
BB	"Scientific Papers - Proceedings of the 39 th Annual Meeting (Wednesday)," featured in <i>The Journal of Nuclear Medicine</i> , Vol. 33, No. 5, May, 1992, pp. 862-864
BC	"Immunology," featured in <i>Proceedings of AACR</i> , Vol. 28, March 1987, p. 391
* BD	"Decreased renal accumulation of biotinylated chimeric monoclonal antibody-neocarzinostatin conjugate after administration of avidin", authored by Otusji, et al., featured as an ABSTRACT in the American Chemical Society, 1998, p. 1
BE	"Radiolabeling of Monoclonal Antibodies with Metal Chelates," featured in <i>Pure & Appl. Chem.</i> Vol. 63, No. 3, 1991, pp. 427-463

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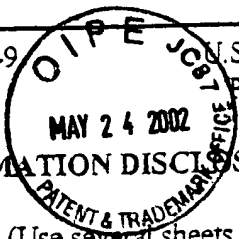
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OTHER INFORMATION (including author, title, date, pertinent pages, etc.)

AU	"Extracorporeal Immunoabsorption From Whole-Blood Based on the Avidin-Biotin Concept Evaluation of a New Method," authored by Michael Garkavii, et al., featured in <i>Acta Oncologica</i> , Vol. 35, No. 3, 1996, pp. 309-312
AV	"Evaluation of Extracorporeal Immunoabsorption for Reduction of the Blood Background in Diagnostic and Therapeutic Applications of Radiolabeled Monoclonal Antibodies" authored by Kristina Norrgren, et al., featured in <i>Antibody, Immunoconjugates, and Radiopharmaceuticals</i> , Vol. 4, No. 4, 1991, pp. 907-914
AW	<i>Radionuclides in Therapy</i> , edited by Richard P. Spencer, et al., 1987 (Table of Contents included)
AX	"Radionuclide Production for the Biosciences," authored by T.J. Ruth, et al., featured in <i>Nucl. Med. Biol.</i> , Vol. 16, No. 4, 1989, pp. 323-336
AY	"Biotinidase," authored by Barry Wolf, et al., featured in <i>Methods in Enzymology</i> , Vol. 184, 1990, pp. 103-111
AZ	"Animal Biotinidase," authored by Jaakko Pispä, featured in <i>Annales Medicinæ Experimentalis Et Biologiæ Fenniae</i> , Vol. 43, 1965, Suppl. 5, pp. 1-39

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AN	"Improved Tumor Imaging with Radiolabeled Monoclonal Antibodies by Plasma Clearance of Unbound Antibody with Anti-antibody Column," authored by James L. Lear, MD, et al., featured in <i>Radiology</i> , Vol. 179, 1991, pp. 509-512
AO	"Radioimmunoabsorption of KC-4G5 Antibody in Peripheral Blood: Implications for Radioimmunotherapy," authored by Timothy K. Johnson, et al., featured in <i>Antibody, Immunoconjugates, and Radiopharmaceuticals</i> , Vol. 4, No. 4, 1991, pp. 385-393
AP	"Extracorporeal Immunoabsorption of Radiolabeled Monoclonal Antibody: A method for Reduction of Background Radioactivity and Its Potential Role During the Radioimmunotherapy of Cancer," authored by David G. Dienhart, et al., featured in <i>Antibody, Immunoconjugates, and Radiopharmaceuticals</i> , Vol. 7, No. 4, 1994, pp. 225-232
AQ	"Immunoabsorption: An Enhancement Strategy for Radioimmunotherapy," authored by Gerald L. DeNardo, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 34, No. 6, June, 1993, pp. 1020-1027
AR	"Biotin Reagents for Antibody Pretargeting. Synthesis, Radioiodination, and in Vitro Evaluation of Water Soluble Biotinidase Resistant Biotin Derivatives," authored by D. Scott Wilbur, et al., featured in <i>Bioconjugate Chem.</i> , Vol. 8, 1997, pp. 572-584
AS	"A General, Extracorporeal Immunoabsorption Method to Increase the Tumor-to-Normal Tissue Ratio in Radioimmunotherapy," authored by Kristina Norrgren, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 34, No. 3, March, 1993, pp. 448-454
AT	"Extracorporeal Whole-Blood Immunoabsorption Enhances Radioimmunotargeting of Iodine-125-Labeled BR96-Biotin Monoclonal Antibody," authored by Michael Garkavij, et al., featured in <i>The Journal of Nuclear Medicine</i> , Vol. 38, No. 6, June, 1997, pp. 895-901

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